

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**(Case No. 03-722)**

In re Application of:	)	
	)	
<b>Schneidinger, et al.</b>	)	
	)	Art Unit: <b>Not yet assigned</b>
Serial No.: <b>To be assigned</b>	)	
	)	Examiner: <b>Not yet assigned</b>
Filed: <b>Herewith</b>	)	
	)	
For: <b>Conjugate of a Tissue Non-Specific Alkaline</b>	)	
<b>Phosphatase and Dextran, Process for the</b>	)	
<b>Production of Such Conjugate and its Use</b>	)	

**INFORMATION DISCLOSURE STATEMENT**

**Commissioner for Patents**  
**PO Box 1450**  
**Alexandria, VA 22313-1450**

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

**McDonnell, Boehnen, Hulbert & Berghoff**  
**300 S. Wacker Drive, Suite 3200**  
**Chicago, IL 60606**  
**312-913-0001**

This Information Disclosure Statement is being filed:

☒ within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. §1.97 (b)

☐ **after** three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):

☐ the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below)

**OR**

☐ the fee of \$180.00 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).

☐ **after** a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" and "Method of Payment of Fees" below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

#### CERTIFICATION

McDonnell, Boehnen, Hulbert & Berghoff  
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312-913-0001

- ☐ The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**FEES**

- ☐ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.

**METHOD OF PAYMENT OF FEES**

- ☐ Attached is a check in the amount of \$180.00
- ☐ Charge Deposit Account No. 13-2490 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

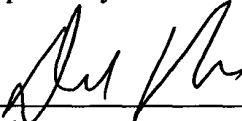
Please charge any underpayment or credit any overpayment in connection with this communication to Deposit Account No. 13-2490. A duplicate copy of this communication is enclosed for this purpose.

**CERTIFICATE OF MAILING VIA EXPRESS MAIL DELIVERY under 37 C.F.R. § 1.10.** I hereby certify that the attached paper of fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this 21<sup>st</sup> day of July, 2003.  
**Express Mail No. EY334708370US.**

Date: \_\_\_\_\_

7/21/03

Respectfully submitted,



David S. Harper  
Registration No. 42,636

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### **U.S. Patent Documents:**

1. Uwe Michaelis, et al., U.S. Patent No. 5,434,067, Issued: July 18, 1995.

### **Article References:**

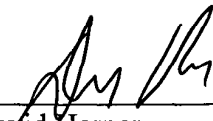
2. Anderson, et al., (1991), Int. J. Cancer, "Binding of epidermal growth factor-dextran conjugates to cultured glioma cells", Vol: 47, pp. 439-444.
3. Balbas, P., (2001), Molecular Biotechnology, "Understanding the art of producing protein and nonprotein molecules in escherichia coli", Vol: 19, pp. 251-267.
4. Bretaudiere and Spillman, (1984), Verlag Chemie, "Methods of enzymatic analysis", Vol: IV, Third Edition, pp. 75-83.
5. Bradford, M.M., (1976), Analytical Biochemistry, "A rapid and sensitive method for the quantitation of microgram quantities of protein utilizing the principle of protein-dye binding", Vol: 72, pp. 248-254.
6. Fukushi, M., et al., (1998), Biochemical and Biophysical Research Communications, "Intracellular retention and degradation of tissue-nonspecific alkaline phosphatase with a Gly<sup>317</sup>→Asp substitution associated with lethal hypophosphatasia", Vol: 246, pp. 613-618.
7. Harris, H., (1989), Clinica Chimica Acta, "The human alkaline phosphatases: What we know and what we don't know", Vol: 186, pp. 133-150.
8. Holmberg, A., et al., (1993), Bioconjugate Chem., "Preparation of sulfhydrylborane-dextran conjugates for boron neutron capture therapy", Vol: 4, pp. 570-573.
9. Hooper, N.M., (1997), Clinica Chimica Acta, "Glycosyl-phosphatidylinositol anchored membrane enzymes", Vol: 266, pp. 3-12.
10. Lilie, H., et al., (1998), Curr. Opin. Biotechnol., "Advances in refolding of proteins produced in E. coli", Vol: 9, pp. 497-501.
11. Lovqvist, A., et al., (1993), Cancer Biotherapy, "Binding, internalization and excretion of TGF $\alpha$ -dextran associated radioactivity in cultured human glioma cells", Vol: 8(4), pp. 345-356.
12. Makrides, S.C., (1996), Microbiological Reviews, "Strategies for achieving high-level expression of genes in escherichia coli", Vol: 60(3), pp. 512-538.
13. Maldonado, O., et al., (1998), J. Clin Gastroenterol, "Extremely high levels of alkaline phosphatase in hospitalized patients", Vol: 27(4), pp. 342-345.
14. Miura, M., et al., (1994), Ann Clin Biochem, "Differences between the sugar moieties of liver- and bone-type alkaline phosphatases: a re-evaluation", Vol: 31, pp. 25-30.
15. Moss, D.W., (1992), Clin. Chem., "Perspectives in alkaline phosphatase research", Vol: 38(12), pp. 2486-2492.

16. Mulivor, R.A., et al., (1985), J. Lab. Clin. Med., "Quantitative analysis of alkaline phosphatases in serum and amniotic fluid: Comparison of biochemical and immunologic assays", Vol: 105(3), pp. 342-348.
17. Nosjean, O., et al., (1997), Biochem. J., "Human tissue non-specific alkaline phosphatases: sugar-moiety-induced enzymic and antigenic modulations and genetic aspects", Vol: 321, pp. 297-303.
18. Oda, K., et al., (1999), J. Biochem., "A general method for rapid purification of soluble versions of glycosylphosphatidylinositol-anchored proteins expressed in insect cells: An application for human tissue-nonspecific alkaline phosphatase", Vol: 126, pp. 694-699.
19. Olsson, P., et al., (1994), Int. J. Cancer., "Internalization and excretion of epidermal growth factor-dextran-associated radioactivity in cultured human squamous-carcinoma cells", Vol: 56, pp. 529-537.
20. Reddy, S., et al., (1995), Biochemistry, " $N^{\Sigma}$ -(Carboxymethyl) lysine is a dominant advanced glycation end product (AGE) antigen in tissue proteins", Vol: 34, pp. 10872-10878.
21. Romagnoli, E., et al., (1998), Clin. Chem. Lab. Med., "Assessment of serum total and bone alkaline phosphatase measurement in clinical practice", Vol: 36(3), pp. 163-168.
22. Silve, C., (1994), Current Opinion in Rheumatology., "Hereditary hypophosphatasia and hyperphosphatasia", Vol: 6, pp. 336-339.
23. Singh, R., et al., (2001), Diabetologia, "Advanced glycation end-products: a review", Vol: 44, pp. 129-146.
24. Sjostrom, A., et al., (1997), Int. J. Cancer., "Binding, internalization and degradation of EGF-Dextran conjugates in two human bladder-cancer cell lines", Vol: 70, pp. 383-389.
25. Thornalley, P.J., et al., (1999), Biochem. J., "Formation of glyoxal, methylglyoxal and 3-deoxyglucosone in the glycation of proteins by glucose", Vol: 344, pp. 109-116.
26. Tietz, N.W., et al., (1983), J. Clin. Chem. Clin. Biochem., "IFCC methods for the measurement of catalytic concentration of enzymes", Vol: 21(11), pp. 731-748.
27. Weiss, M.J., et al., (1988), The Journal of Biological Chemistry, "Structure of the human liver/bone/kidney alkaline phosphatase gene", Vol: 263(24), pp. 12002-12010.
28. Weiss, M.M., et al., (1986), Proc. Natl. Acad. Sci. USA, "Isolation and characterization of a cDNA encoding a human liver/bone/kidney-type alkaline phosphatase", Vol: 83, pp. 7182-7186.
29. Wiwanitkit, V., (2001), BMC Family Practice 2001, "High serum alkaline phosphatase levels, a study in 181 Thai adult hospitalized patients", Vol: 2(2), 4 page article.

In accordance with MPEP Sections 609 and 707.05(b), it is requested the document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Date: 7/21/03

Respectfully Submitted,

By:   
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<b>FORM PTO-1449</b> (Rev. 2-32)	<b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>	<b>Atty. Docket No.</b> 03-722	<b>Serial No.</b> To be assigned
<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)		<b>Applicant:</b>	
		Schneidinger, et al.	
		<b>Filing Date:</b>	<b>Group:</b>
		Herewith	To be assigned

### U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	5,434,067	7/18/95	Uwe Michaelis, et al.			7/30/93

### FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclasses	Translation	
							Yes	No

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

	2.	Anderson, et al., (1991), Int. J. Cancer, "Binding of epidermal growth factor-dextran conjugates to cultured glioma cells", Vol: 47, pp. 439-444.
	3.	Balbas, P., (2001), Molecular Biotechnology, "Understanding the art of producing protein and nonprotein molecules in escherichia coli", Vol: 19, pp. 251-267.
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	5.	Bradford, M.M., (1976), Analytical Biochemistry, "A rapid and sensitive method for the quantitation of microgram quantities of protein utilizing the principle of protein-dye binding", Vol: 72, pp. 248-254.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

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6.	Fukushi, M., et al., (1998), Biochemical and Biophysical Research Communications, "Intracellular retention and degradation of tissue-nonspecific alkaline phosphatase with a Gly <sup>317</sup> →Asp substitution associated with lethal hypophosphatasia", Vol: 246, pp. 613-618.
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(Rev. 2-32)

**U.S. Department of Commerce**  
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**Atty. Docket No.**

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